

Project Plan Cell Bank Storage

BIOMEVA GmbH

The details listed in chapter 1 and 2 are intended to give an overview of the information required before storing vials at BIOMEVA. Chapter 3 describes the different phases of the project and its typical timelines. Contacts for cell banking activities are listed in chapter 4. Chapter 5 provides a survey of the storing features at BIOMEVA.

1. BASIC INFORMATION CELL CLONE AND EXPRESSION CONSTRUCT

The following information on the genetically modified organism is requested from the client according to the German Genetic Engineering Act. BIOMEVA provides the client with appropriate forms that can be filled. Please note that the provided information will be held strictly confidential by BIOMEVA.

Host strain: Source of cells (laboratory or culture collection), citation of relevant references from scientific literature

- species and strain
- genotypic and phenotypic characteristics
- pathogenicity, toxin production

Donor: Description of the origin of the nucleotide sequence coding for the protein (source of the cell)

Vector: Description of the source and function of component parts of the expression construct:

- description of the vector (name, size, structure, source of the plasmid)
- graphic presentation of expression vector with relevant genetic elements and unique restriction sites indicated
- antibiotic resistance genes
- promoter, operator (description and origins)
- detailed component map
- nucleotide sequence of the coding region and associated flanking regions

Risk assessment from client

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2. BASIC INFORMATION CELL BANK STORAGE

The following information is requested in order to assess the scope of storage and to perform a feasibility study in advance:

- Type of cell bank to be stored Master [Cell Bank (MCB) and/or Working Cell Bank (WCB)].
- Number of vials to be stored.
- Type of vials/boxes the customer uses currently for storing (please indicate the manufacturer and the article number of the vials and boxes)

Biomeva prefers Nunc cryovials (Sterile 1.8 mL Cryotubes SI, Nunc, Art.-Nr.:377267) and the corresponding storage system (Cryopreservation Box - System 100 for 10 x 10 Vials, Nalgene, Art.-Nr: 5026-1010, L x W x H = 133 x 133 x 52mm).

But please note that Biomeva is flexible regarding vials and storage systems. Therefore, if you use other cryovials or other storage systems please inform us that we can investigate the feasibility.

- Confirmation of culture purity and the absence of free bacteriophage / lysogenic prophage by providing an appropriate CofA.

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3. GENERAL PROJECT STEPS

STEP	TIMEFRAME	ACTIVITY	PREREQUISITES	RESPONSIBILITY
1	Week 1	Inquiry for cell bank storage to BIOMEVA	-	Client
2	Week 1	Confirmation of receipt of inquiry, forwarding of information & questionnaire to client Issue of quotation	-	BIOMEVA BIOMEVA
3	Week 2-3	Completion of Basic Information Request (see chapter 1 and 2 of this document)	-	Client
4	Week 2-3	Issue of contract, approval by client	Completion of Basic Information Request by client	Client / BIOMEVA
5	Week 4	Shipment of vials on dry ice from client to BIOMEVA	Signed contract	Client
6	Week 4	Storage of vials in the gas phase of liquid nitrogen	-	BIOMEVA

Note: This timeline can be shortened or extended primarily due to the progress in providing information on the genetically modified organism (see chapter 1) and due to the progress in providing technology transfer information (see chapter 2).

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4. CONTACTS

Please contact the following persons at BIOMEVA if you require additional assistance as for cell banking activities:

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CEO, Managing Director	Head Fermentation
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5. FEATURES

At BIOMEVA, we know that the safety and security of your cell banks are your highest priority, so we have made it ours. For over eight years now, BIOMEVA has been storing microbial cell lines under current Good Manufacturing Practices (cGMP) in our biorepository to ensure that when they are needed, they are available. BIOMEVA has incorporated a number of practices that keep risk to an absolute minimum when it comes to counting on long-term reserves.



Cell bank storage room (class 100.000). Cells are stored in the gas phase of liquid nitrogen in temperature monitored containers connected to an alarm system.

Secure Cell Storage Service

Our facility is monitored 24 hours a day, seven days per week. Our cGMP liquid nitrogen freezers provide a secure storage environment that maintains temperatures below -150°C . In accordance with recommendations from the Centers for Disease and Prevention (CDC), the samples are stored in the vapor phase of liquid nitrogen.

Safety Precautions

Before any cell bank is placed in our freezers, it must be certified as being free from bacteriophages and tested for purity. As an added precaution, each bank can be divided equally and stored in separate liquid nitrogen freezers so that in the rare event of a complete freezer malfunction, a second group of vials is still available for subsequent use.

Monitoring Systems

Freezer temperatures are monitored with redundant monitoring systems 24 hours per day. Each working day, temperature data are monitored manually to corroborate electronic readings.

Security Control

Access to our facility is tightly controlled and only trained and authorized BIOMEVA staff have access to the biorepository storage area.

Alarm Response

The optional reliability of the temperature monitoring system is ensured by a daily automatic control call. Staff are on call 24 hours a day.